

[54] DILATING APPARATUS AND METHOD

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[51] Int. Cl. A61m 29/00

[58] Field of Search. 128/341, 343, 348, 349 R, 128/350

[56] References Cited

UNITED STATES PATENTS

3,196,876 7/1965 Miller 128/343
2,024,982 12/1935 Scott 128/349 R

FOREIGN PATENTS OR APPLICATIONS

258,116 3/1913 Germany 128/276

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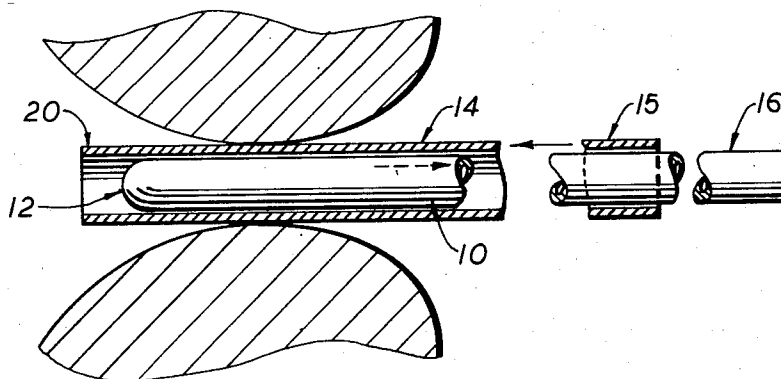
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[57] ABSTRACT

To accurately dilate tissue preparatory to introducing medical instruments therein, an elongated, flexible probe of uniform diameter having a rounded insertion tip is employed to sound the tissue. An elongated, hollow, flexible dilator is then slidably passed over the probe to coaxially abut the probe insertion tip. The probe is withdrawn through the dilator. A second, hollow, flexible dilator is coaxially inserted over the first dilator and the first dilator is withdrawn from the second dilator. Thereafter the procedure is repeated with dilators of successively larger internal diameter such that a final dilator is implanted which stretches the tissue to a desired degree. A medical instrument may thereafter be passed through the final dilator in proper alignment for treating purposes. The final dilator is thereafter withdrawn leaving the medical instrument to be utilized as needed. The apparatus provides for accurate insertion of subsequent dilators and the desired medical instrument with reduced patient trauma.

1 Claim, 5 Drawing Figures



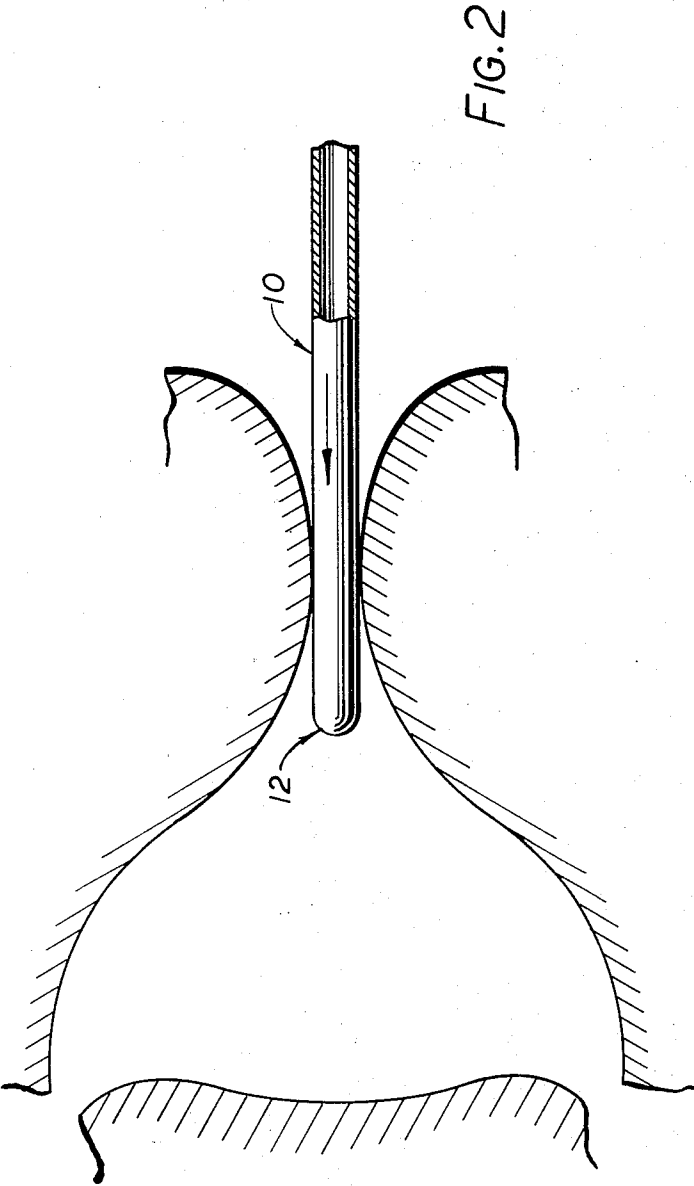
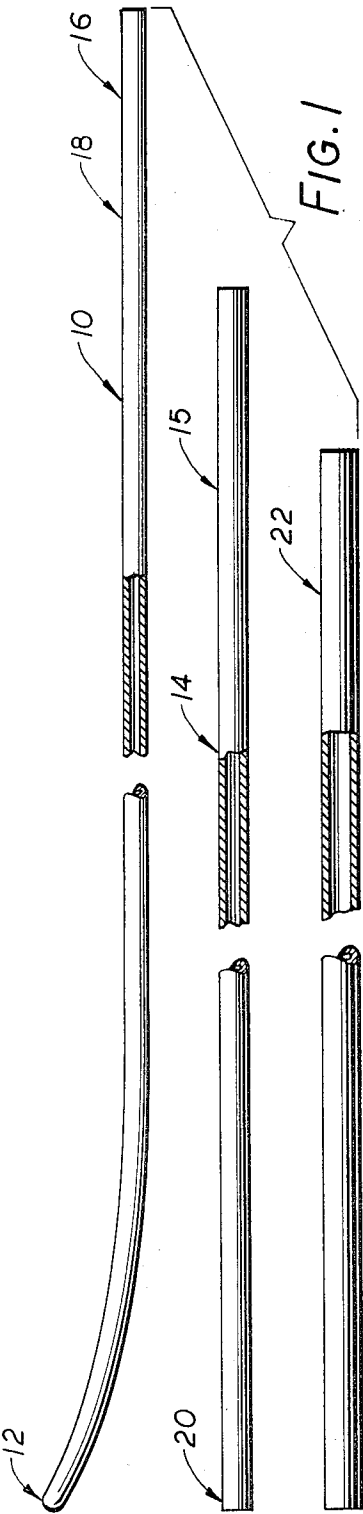


FIG. 3

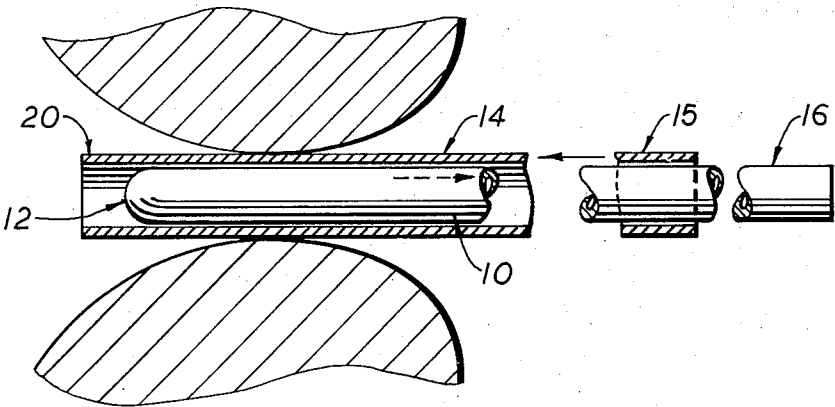


FIG. 4

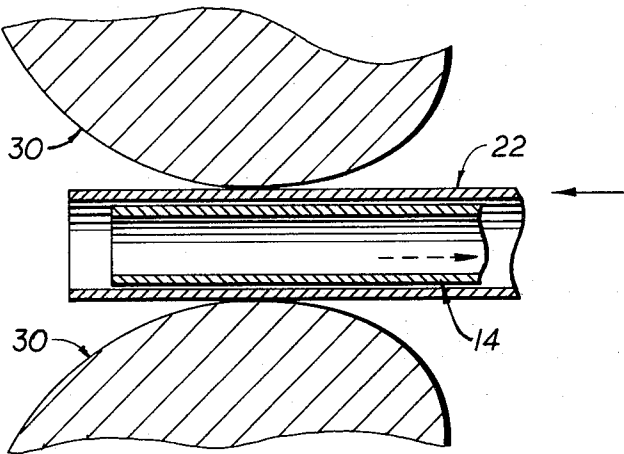
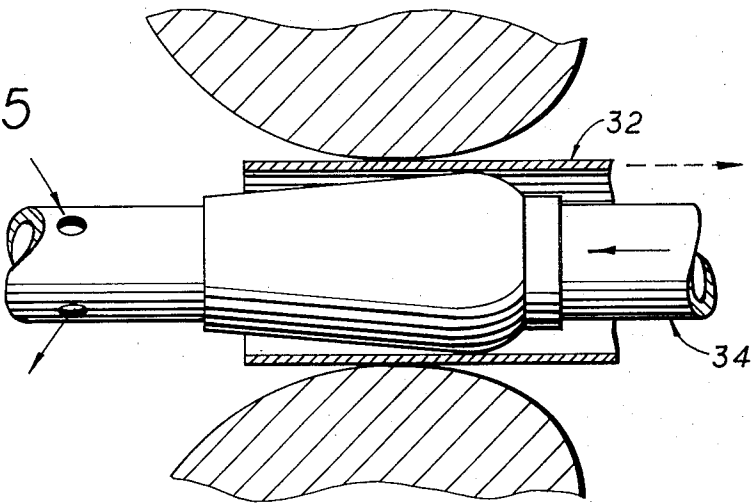


FIG. 5



DILATING APPARATUS AND METHOD

BACKGROUND OF THE INVENTION

The present invention relates to a dilating apparatus permitting extremely accurate insertion and dilation with significantly reduced patient trauma. More particularly, it relates to a dilating apparatus permitting accurate insertion of medical instruments with reduced patient trauma.

In order to treat various internal portions of the body it is often necessary to dilate stretchable tissue and insert the required medical instrument into the cavity to be treated. For example, dilation of the cervical canal is required in the performance of several female medical procedures. In order to insert an intrauterine coil, curettes or the Gravlee JET WASHER described in U.S. Pat. No. 3,527,203, there must be an extremely accurate dilation and insertion procedure. Conventionally, this has been accomplished by employing a series of Hegar dilators. These instruments are round, rigid and metal probes of graduated sizes which are sequentially inserted and removed from the cervical os, each probe larger in diameter than the other. Because of the difficulty of passing an instrument into the uterine cavity, the cervix is usually dilated to a point larger than the instrument itself. Often this procedure can be painful, usually requiring anesthetic.

In many cases there is considerable pain associated with the inaccurate insertion of the metal probes and/or medical instruments. Often the passage to be dilated closes after removal of the conventional dilators. Finding the originally dilated opening in the partially closed passage can be difficult, painful and time consuming.

Other body cavities also require dilation prior to treatment. The urinary tract in both males and females is often probed and dilated as part of routine medical procedure. Dilation of the Sphincter of Oddi to facilitate passage of residual stones or debris left in the common duct is a common procedure.

In U.S. Pat. No. 3,196,876, issued to Miller, it has been proposed to employ a metal probe having a rigid handle and a bulbous tip on the guide probe. Thereafter, a series of sleeves are inserted over the imbedded guide probe to dilate the passage. The sleeves also have an enlarged, oval-shaped tip. It is impossible to insert a medical instrument into the dilated passage employing the Miller device without first withdrawing all the dilators and, thereafter, also withdrawing the implanted probe. This procedure must be followed because the bulbous tip on the Miller probe does not permit it to be removed from the passage without the prior removal of the subsequently inserted sleeves. Should the Miller dilated passage relax and close, after removal of the sleeves and probe, then insertion of a medical instrument therein can be difficult, traumatic and time consuming for both the doctor and patient.

Particularly, on the battlefield there is an urgent need for a dilation apparatus that would allow rapid and accurate dilation of a bullet wound passage and the subsequent introduction of a medical instrument to remove the bullet. Conventional dilating apparatus, particularly, rigid dilating apparatus, do not permit this procedure to be carried out rapidly, accurately and with reduced trauma to the patient.

SUMMARY OF THE INVENTION

It is, therefore, a primary object of the present invention to provide a dilating apparatus adapted to dilate a passage with increased accuracy and reduced trauma as compared to prior art apparatus.

It is another object of the invention to provide a dilating apparatus which permits the rapid and accurate insertion of a medical instrument into an internal cavity while the opening to the cavity remains in a dilated state, greater than the size of the medical instrument.

It is also an object to provide a method for accurately dilating a body passage to permit an immediate, accurate, insertion of a medical instrument through a final dilator into the passage.

The above and other objects are obtained by the combination of an elongated, flexible probe of uniform diameter and at least one elongated, hollow, flexible dilator adapted to be slidably guided over the probe wherein the probe and dilator are removably mounted with respect to each other. The probe has a rounded insertion tip which permits the probe to be freely retracted through the surrounding hollow dilator, after sounding.

To expand the probed passage a plurality of elongated, hollow, flexible, uniform dilators are provided wherein successive dilators are adapted to be slidably mounted over each other. The dilator of least diameter is adapted to be slidably guided along the probe to at least concentric abutment with the probe insertion tip. The probe and dilator of least diameter are removably mounted with respect to each other. Likewise, the dilators of successively increasing diameter are removably mounted with respect to each other.

A method is also provided for accurately dilating stretchable tissue as body orifices, ducts or wounds with reduced trauma and for accurately introducing medical instruments into the dilated orifices, ducts or wounds. The method includes inserting an elongated, flexible probe of uniform diameter into the stretchable tissue to a predetermined position therein. The probe has a rounded insertion tip. A first elongated flexible hollow dilator is inserted over the probe up to the insertion tip of the probe. Then, the flexible probe is removed from the tissue through the dilator.

Next, a second elongated, hollow, flexible dilator is inserted over the first dilator co-extensive with the first dilator. The second dilator is of slightly larger internal diameter than the external diameter of the first dilator. Thereafter, the first dilator is removed from the tissue through the second dilator. Dilators of successively greater internal diameter are sequentially inserted over dilators of lesser diameter and the smaller, inner dilators removed therefrom, until the tissue is stretched to a predetermined size by a final dilator.

Thereafter, a desired medical instrument, such as a curette or JET WASHER or even an intrauterine coil is passed through the final dilator. The final dilator is withdrawn from the tissue such that the medical instrument remains in a predetermined position for treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the present invention will be readily apparent from the following detailed description taken in conjunction with the accompanying drawings wherein:

FIG. 1 is a fragmentary view of the flexible probe and a pair of dilators of successively greater diameter;

FIG. 2 is a schematic view illustrating the positioning of the probe of FIG. 1 in a cervical canal;

FIG. 3 is a schematic view illustrating the withdrawal of the probe from the cervical canal after insertion of a dilator over the probe;

FIG. 4 is a schematic view illustrating the withdrawal of the dilator subsequent to the enlargement of the cervical canal by the insertion of a dilator with a larger diameter; and

FIG. 5 is a schematic view illustrating the enlargement of the cervical canal by a final dilator to a predetermined size and the placement of a Jet Washer therein.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawings and, more particularly, to FIG. 1, there is illustrated elongated, smooth, flexible probe 10 of uniform external and internal diameter having a rounded insertion tip 12. In order to facilitate exploration and sounding a pre-formed curve is formed into the body of the probe adjacent the insertion tip 12. The probe is fabricated from smooth, flexible materials, as flexible thermoplastic resins, such as polyethylene, polypropylene, vinyl, polyvinyl chloride, and copolymers and homopolymers of the same and the like. The probe may be formed from a solid or hollow tube. It is preferred that the probe be manufactured from non-irritating materials.

The probe is employed in conjunction with at least one hollow, flexible tubular dilator 14. It is preferred that both probe 10 and dilator 14 are of such uniform diameter such that dilator 14 may be inserted over the proximal end 16 of probe 10 and advanced down the external surface 18 of the probe until the distal end 20 of the dilator is coaxial with the probe insertion tip 12. For this and other purposes, it is preferred that dilator 14 be formed from flexible, non-irritating plastic resins such as vinyl, polyethylene, polypropylene, polyvinyl chloride and homopolymers and copolymers thereof. In general, dilator 14 should be of sufficient thickness in order that it be able to withstand the pressures involved in introducing the dilator into the desired body cavity over the probe.

In order to permit dilation to a desired degree, additional dilators are provided, as required. The succeeding dilators are formed from flexible materials as described hereinbefore and are uniform diameter, each dilator of increasingly larger internal diameter. As illustrated in FIG. 4, dilator 22 is of sufficient internal diameter, as to slidably pass over dilator 14.

A workable dilating apparatus includes a probe formed from a flexible vinyl polymer. The probe is 12.5 inches long having a curved portion with a radius of 4 inches at the distal end. The internal diameter of the probe is 0.040 inch and the outer wall of the probe is 0.024 inch thick. A first dilator adapted to be slidably mounted over the probe is 6.6 inches long. The dilator is formed from a vinyl polymer and has an internal bore of 0.095 inch and a thickness of 0.030 inch. Additional

dilators of the same material having successively larger internal diameters are provided, as needed.

The above described dilating apparatus is useful for various medical procedures. The apparatus may be employed for dilating or enlarging the cervical canal, the urinary tract in both males and females and body ducts, as well as wound cavities. After dilation, various medical instruments such as an intrauterine coil, curettes, Jet Washers, forceps and the like may be introduced into the cavity, held retracted by the final dilator. Thereafter, the final dilator is withdrawn thereby allowing accurate insertion of the instrument.

Turning now to FIGS. 2-5 there is illustrated a medical procedure wherein the cervical canal is probed and dilated. Thereafter, a Jet Washer, the subject of U.S. Pat. No. 3,527,203, is inserted therein. As shown in FIG. 2 the distal tip 12 of probe 10 is inserted into the cervical os. The opening is probed and the directions determined. As illustrated in FIG. 3, dilator 14 (solid arrow) is inserted over the proximal end 16 of probe 10 and passed over the outer surface of the probe until in approximate coaxial alignment with distal end 12 of the probe. In this manner the dilator is accurately inserted into the cervical canal with a minimum of movement and a corresponding reduction in patient trauma. Next, probe 10 is withdrawn (dotted arrow) from the bore of dilator 14.

At this point, if desired, a syringe adapter (not shown) may be connected to the proximal end 15 of the dilator 14. If desired, the syringe adapter may be permanently connected to the proximal end 15 of the dilator. Thereafter, a syringe containing a desired medicament may be connected to and injected into the bore of dilator 14, thus introducing a desired medication into the uterine cavity.

As illustrated in FIG. 4 the cervical canal 30 is enlarged by the sequential passage and removal of successive dilators of increasing internal diameter. As depicted in FIG. 4 dilator 14 is withdrawn (dotted arrow) from the cervical canal after having served as a guide for the introduction of dilator 22 (solid arrow). After the cervical canal has been enlarged to a desired degree by the use of successive dilators, as depicted in FIG. 5, a medical instrument, the Gravlee Jet Washer 34, is inserted through the bore of the final dilator 32 (solid arrow). For this purpose, final dilator 32 should be of sufficient internal diameter to permit the free passage of the Jet Washer 34. The dilator is then withdrawn (dotted arrow) leaving the instrument 34 in accurate alignment. In use, a solution is discharged through holes in the Washer and thereafter collected through other orifices. The collected solution contains cell specimens.

The above described procedure is applicable with obvious modifications for the medical procedures outlined hereinabove. For example, a small fine probe may be employed to sound a bullet wound to locate a bullet. Next, a hollow dilator is introduced over the original probe to retract the tissue and vessels and the probe is withdrawn. A dilator of larger internal diameter is slidably engaged over the dilator to further retract the tissue and the first dilator is removed. Thereafter, a series of dilators are slidably engaged over successive dilators to further retract the tissue and vessels to a point where the bullet may be removed through the inside bore of the final dilator.

Likewise, in a tubal ligation only a small incision need be made in the abdomen. A series of dilators as

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described hereinabove can be employed to stretch the tissue to a point where the final dilator would have increased the diameter of the incision sufficiently to a point where the fallopian tube is exposed. The tube is tied off, the dilator removed, with only one or two sutures necessary to close the incision. 5

While we have described a somewhat preferred form dilating apparatus and method, it is to be understood that various modifications may be made herein without departing from the spirit of the invention as defined in the appended claims. 10

We claim:

1. A method of facilitating entrance through a body orifice and dilation of the orifice thereafter to a desired degree comprising: 15

inserting an elongated flexible plastic probe of uniform diameter throughout its length and having distal and proximal ends into the body orifice to the desired extent;

shifting at least one elongated hollow flexible plastic dilator member of uniform inner and outer diameter and open at both ends and having a slightly 20

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larger inner diameter than the outer diameter of the probe axially with respect to the probe from the proximal end to the distal end thereof into a concentric position therewith after the probe has been inserted into the orifice so as to dilate the orifice;

facilitating dilation by providing a probe and each dilator member which are conformable in configuration to the orifice; and

removing the probe from within the dilator member by shifting the probe from the concentric relationship with the dilator member in the orifice so as to remove the probe while retaining the dilator member in the dilated orifice with the dilator member independently retaining the orifice in the dilated condition, providing an access passageway through the hollow dilator member to facilitate insertion and removal of instruments to and from the interior of the body, and providing a support for insertion of a further dilator member when one is to be employed.

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